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| Office Action Summary | Application No. | Applicant(s) | |
| | 10/532,319 | BARON ET AL. | |
| | Examiner | Art Unit | |
| | Diana B. Johannsen | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 1-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0505;0406;0606</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application is a 371 of PCT/US03/38783, filed December 5, 2003. It is noted that the search report and international preliminary examination report for the PCT application are present in the application file and have been considered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on EP 02027272.0 filed December 6, 2002 and EP 03007458.7 filed April 4, 2003. It is noted, however, that applicant has not filed a certified copy of these applications (and that none are present in the application file), as required by 35 U.S.C. 119(b).

Information Disclosure Statement

3. The information disclosure statement filed April 7, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, complete copies of the references identified by numbers 11 (Humar) and 19 (Reid) were not provided. Accordingly, those references have not been considered.

4. The information disclosure statement filed April 7, 2006 also fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each publication listed that is not in the English language. Accordingly, the reference identified by number 16, which is in French, has not been considered.

5. The information disclosure statement filed May 23, 2005 also fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Accordingly, the references identified by numbers 11 and 15, which are in German, have not been considered.

Claim Objections

6. Claims 3-8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

7. Claims 1-2 are objected to because of the following informalities: the claims are not properly punctuated so as to delineate the steps of the claimed method. For example, the only punctuation in the claims (other than a period at the end of each claim) is a series of dashes. Further, claim 2 refers to "claim1" rather than "claim 1." Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 are indefinite because it is not clear how the method steps set forth in the claims result in “analyzing the presence of a bacterial pathogen in a clinical sample,” as required by the preamble of claim 1. For example, it is not clear how steps of determining amounts of nucleic acid relate to analyzing “the presence of a bacterial pathogen.” Further, while the step of “isolating nucleic acid” in claim 1 references “said sample” of the claim preamble, the subsequent steps of the method never refer either to the clinical sample or to the nucleic acid isolated therefrom. Clarification is required.

Claims 1-2 are indefinite over the recitation of the term “determining” because it is not clear whether this term requires an actual, manipulative method step, or whether the claims might encompass, e.g., a mental step or thought process. Thus, it is not clear what actual, active steps are required by the claimed method.

Claim 2 is indefinite over the recitation of the language “determining whether said amount....remains under a second predetermined cut off value.” Particularly, it is not clear what the term “remains” means within the context of the claim – does this language simply mean that the “amount of nucleic acid” exceeds one value and falls below another value at a single point in time, or is the use of the term “remains” intended to indicate a measurement taken, e.g., at a later point in time as compared to the determination of the “first predetermined cut off value?”

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Angen et al (Journal of Clinical Microbiology 39(1):260-265 [1/2001])(reference cited in the IDS of April 7, 2006).

Angen et al disclose a method in which the presence of *Actinobacillus pleuropneumoniae* in porcine tonsil scrapings is analyzed (see entire reference, particularly page 261). The method of Angen et al comprises steps of isolating total nucleic acid from the sample and quantifying *omlA* gene sequences contained therein via a 5' nuclease assay, and further comprising determining whether the amount of *omlA* nucleic acids produced by amplification exceed a certain ΔR_n value and fall below a certain C_t value (see entire reference, particularly pages 261-263). It is an inherent property of the ΔR_n value of Angen et al that it constitutes a type of "first predetermined cut off value," and it is an inherent property of the C_t value of Angen et al that it constitutes a type of "second predetermined cut off value." Thus, Angen et al teach all the steps set forth in the instant claims, and anticipate the claimed invention.

Drawings

12. The drawings are objected to because Figure 1 contains a typographical error, referring to "sampl s" rather than "samples." Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be

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labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoorfar et al (Journal of Clinical Microbiology 38(9):3429-3435 [9/2000])(cited in the IDS of April 7, 2006) disclose a "gray zone" of ΔR_n values "for retesting of possible suspect results" (see entire reference, particularly page 3433, right column).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", with a long horizontal flourish extending to the right.

Diana B. Johannsen
Primary Examiner
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